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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,711	04/05/1999	TAKESHI SAKAI	I/F3511PTUS	1469

513 7590 03/19/2002

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/269,711

Examiner

Shengjun Wang

Applicant(s)

SAKAI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 28, 2001 is acknowledged.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 40-43 and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Winget (US Patent No. 5,620,962, of record) for reasons set forth in the prior office action.

3. Claims 40 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazawa et al. (of record) or Nojima et al. (JP 60-19716, IDS, AA) for reasons set forth in the prior office action.

Claims Rejections 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Winget (US Patent No. 5,620,962) and Yazawa et al. (IDS, AB), Nojima et al. (JP 60-19716,

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IDS, AA) in view of Nakai et al. (US Patent 5,672,603), and Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993) set forth in the prior office action.

Applicants' amendments and remarks submitted December 28, 2001 have been fully considered, they are persuasive to overcome the rejection under 35 U.S.C. 112, but are not persuasive for rejection under 35 U.S.C. 102 and 103 for reasons discussed below.

Applicants assert that the examiner is misapplying the principle of inherency under U.S. practice, state that a method of use for a known compound may be patentable, citing MPEP 2112 and Ex parte Wagner, 88 U.S.P.Q. 217. The examiner agrees that new and unobvious use of old compounds may be patentable. However, the instant application is in a different situation. Note MPEP 2112 further states "when claim recites using an old composition or structure and the 'use' is directed to a results or property of that composition or structure, then the claim is anticipated." The claimed invention use the *same* old compound (glycerolipid and/or glyceroglycolipid) in an *exact same* procedure (administering the compound to an individual). The difference is that the claimed invention is directed to a results or property (inducing apoptosis). The claimed invention is therefore clearly anticipated by the references.

Applicants assert that it is unobvious for using the glycerolipid and/or glyceroglycolipid for inducing apoptosis because Yazawa and Nojima teach the compounds have no cytotoxicity, and therefore do not expressly teaches the apoptosis mechanism. Applicants improperly interpret 'no cytotoxicity' as no apoptosis (self programmed death). The examiner thinks it opposite. Note, as stated by Nakai et al., there are only two type mechanism are involved in cell death: necrosis and apoptosis. (column 1, lines 36-67). Glycerolipid and/or glyceroglycolipid are known

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least some cancer cells. Since glycerolipid and/or glyceroglycolipid have no cytotoxicity and are known of “host-mediated activation of the immune system”, they would not cause the death of cancer cell through necrosis. The only possible way they make cancer cell death is through the other mechanism, i.e., apoptosis. The detailed mechanism may be different, but they do induce apoptosis. Therefore, cited prior arts have provided reasonable suggestion that glycerolipid and/or glyceroglycolipid induce apoptosis, particularly in treating cancer.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235. .



Shengjun Wang

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March 15, 2002



RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200